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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,876	10/05/2001	John P. McKearn	CU-2557 RJS	2805

7590

07/29/2004

Mr. James M. Warner
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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,876

Applicant(s)

MCKEARN ET AL.

Examiner

Cybille Delacroix-Muirheid

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
4a) Of the above claim(s) 5-14, 16-18, 23 and 25-27 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-4, 15, 19-22 and 24 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 01/21/04.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The following is responsive to Applicant's amendment received March 26, 2004.

No claims are cancelled. New claims 23-27 are added. Claims 1-27 are currently pending. Claims 5-14 and 16-18, 23, 25-27 are withdrawn from consideration.

Information Disclosure Statement

Applicant's Information Disclosure Statement received Jan. 21, 2004 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Response to Arguments

The previous claim rejection under 35 USC 112, first paragraph, set forth in paragraph 1 of the office action mailed Dec. 31, 2003, **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 112, second paragraph, set forth in paragraphs 2-5 of the office action mailed Dec. 31, 2003 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

Applicant's arguments traversing the previous claim rejection under 35 USC 103(a) set forth in paragraph 6 of the office action mailed Dec. 31, 2003 have been carefully considered but are moot in view of the following new ground of rejection.

The previous claim rejection under 35 USC 103(a) set forth at paragraph 6 of the office action mailed Dec. 31, 2003 **is withdrawn** in view of the following new ground of rejection.

New Ground(s) of Rejection

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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1. Claims 1-4, 15, 19-22, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bender et al., 5,753,653 (already of record) in view of Comis et al. (submitted by Applicant in IDS of Jan. 21, 2004) and Finley, Chapter 94/ Lung Cancer.

Bender et al. disclose a method for inhibiting the activity of metalloproteinases by administering an effective amount of a compound represented by Formula (I), wherein a specific compound to be administered is disclosed at line 24 of Table I (elected compound). Furthermore, Bender et al. teach that the compounds may be useful in treating tumor growth, invasion or metastasis, wherein a specific tumor to be inhibited may be a lung tumor. Please see the abstract; Table I, claims 15-16; col. 45, lines 44-67.

Bender et al. do not teach combining the administration of the metalloproteinase inhibitor with radiation therapy; however, the Examiner refers to (1) Comis et al., which disclose that in the 1980's a beneficial therapeutic regimen using a combination of radiation and chemotherapy was used in small-cell lung cancer, resulting in an extension in the survival rate of patients (please see page 44, second and third column; page 45, second column, second full paragraph) and (2) Finley, which teaches that in the treatment of small cell lung cancer, a very radiosensitive tumor, a combination of chemotherapy and radiation was employed. Finley discloses that the reason behind using such a therapeutic approach is that the radiation would target the tumor in the chest area whereas the chemotherapy would target any metastasis systemically (please see page 1364, **Radiation**, first full paragraph to page 1365, line 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Bender et al. to combine the

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metalloproteinase inhibitor with radiation therapy because both Comis and Finley establish that chemotherapy in combination with radiation therapy has long been a conventional therapeutic approach for the treatment of lung cancer. Additionally, based on the beneficial results obtained from combination treatment as well as the inhibitory properties of the metalloproteinase inhibitor, one of ordinary skill in the art would reasonably expect the metalloproteinase inhibitor in combination with radiation therapy to effectively treat a patient suffering from lung cancer thereby extending a patient's survival rate. Finally, such a modification would have been motivated by the reasonable expectation that the metalloproteinase inhibitor of Bender et al. would target any metastasis systemically while the radiation therapy would target the primary site of the lung cancer thus increasing the response rate and comprehensively treating the patient suffering from lung cancer.

Concerning claims 19-22, it would have been obvious to one of ordinary skill in the art to either sequentially or simultaneously administer the two forms of therapy with the reasonable expectation that either form of administration would effectively treat a patient suffering from lung cancer.

Conclusion

Claims 1-4, 15, 19-22, 24 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is

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571-272-0572. The examiner can normally be reached on Mon-Thurs. and every other Friday from 8:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

July 28, 2004


Cybille Delacroix-Muirheid
Patent Examiner Group 1600